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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,906	01/16/2004	Gennady Nisnevich	1662/607041	1521
26646	7590	05/06/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/759,906	Applicant(s) NISNEVICH ET AL.	
	Examiner Rita J. Desai	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-32, 36-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 is/are rejected.
- 7) ☒ Claim(s) 34, 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/04; 11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

RD

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DETAILED ACTION

Election/Restrictions

Applicants elected group VII claims 33-35 of the restriction, without traverse.

Applicants are required to cancel the non-elected claims in their response.

Applicants preserve their right to file a divisional on the cancelled non-elected claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5541209

Spinale.

The reference discloses a process of making Irbesartan from the trityl protected tetrazole. See column 5 lines 7 to 35.

The triphenyl derivative is made acidic and then neutralized and then separated. The second aqueous solution is acidified and recovering the Irbesartan.

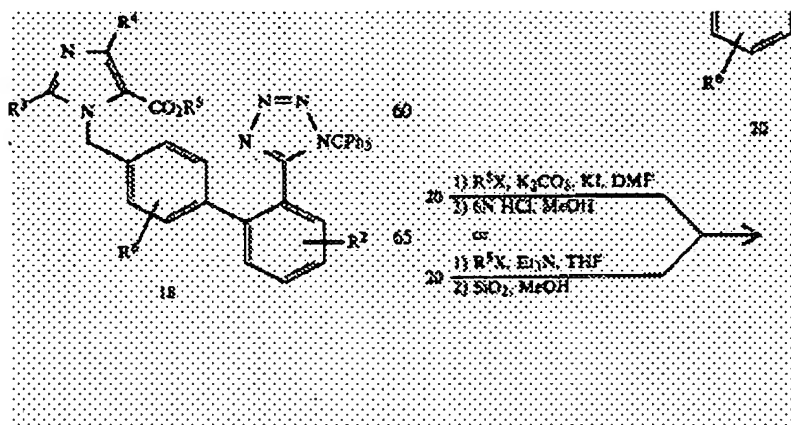
Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by

US 5310929 Ardecky et al

US 5270317 Bernhart et al .

US 5310929 Ardecky et al discloses the process in scheme 5 columns 11 and 12.

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US 5270317 Bernhart et al discloses the process in column 21.

21

B) 2-n-Butyl-4-spirocyclopentane-1-[(2'-(triphenylmethyl)tetrazol-5-yl)biphenyl-4-yl)methyl]-2-imidazolin-5-one

1.56 g of the previous product, 2.6 g of tributyltin azide and 30 ml of xylene are refluxed for 66 hours. The xylene is then evaporated off and the residue is dissolved in 20 ml of DCM and 5 ml of THF with the addition of 0.8 ml of 10N sodium hydroxide solution and, after stirring for 30 minutes, 2.5 g of trityl chloride, and the mixture is stirred for 26 hours. After evaporation of the solvents, the residue is taken up in ethyl acetate, washed with water and then with a 3% solution of potassium bisulfate and water. It is dried and evaporated. The residue is chromatographed on alumina using a hexane/ethyl acetate mixture (9/1; v/v) as the eluent to give 1.97 g of the expected product. M.p. = 150°-152° C.

C) 2-n-Butyl-4-spirocyclopentane-1-[(2'-(tetrazol-5-yl)biphenyl-4-yl)methyl]-2-imidazolin-5-one

1.96 g of the product prepared in the previous step are dissolved in 10 ml of methanol and 10 ml of THF. After the reaction medium has been cooled to 5° C., 1.5 ml of 4N hydrochloric acid are added and the mixture is stirred for 3 hours at RT and 1 hour at 30° C. After evaporation of the solvents, the residue is taken up in water and the pH is brought to 12 by the addition of 10N sodium hydroxide solution. The aqueous phase is extracted with ether, toluene and ether again. The aqueous phase is acidified to pH 2 by the addition of 1N hydrochloric acid and then extracted with ethyl acetate and the extract is dried and evaporated. The white solid obtained is dried at 50° C. under 0.05 mm of mercury to give 840 mg of the expected product. M.p. = 180°-181° C.

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The triphenyl derivative is made acidic and then neutralized and then separated. The second aqueous solution is acidified and recovering the Irbesartan.

Conclusion

The claim 33 is rejected.

Claim 34 and 35 are objected to since they are dependent from a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

R. Desai
5/3/05

R.D.
May 3, 2005